IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

MEDYTOX INC., Plaintiff, v. DAEWOONG CO., LTD. and DAEWOONG PHARMACEUTICAL CO., LTD. Defendants.	COMPLAINT Case No. _____ **REDACTED**

I. INTRODUCTION

1. Plaintiff, Medytox Inc. ("Medytox"), by counsel, files this Complaint against Daewoong Co., Ltd. and its subsidiary Daewoong Pharmaceutical, Co. Ltd. (together, "Daewoong").

2. Medytox is a Korean manufacturer of botulinum neurotoxin ("BTX") products. BTX products are biologics that are known for their aesthetic indications (as the BOTOX® Cosmetic product made by Allergan is popularly known for) and also have therapeutic applications.

3. Daewoong misappropriated Medytox's manufacturing process trade secrets for making BTX products and used them to secure a patent from the U.S. Patent and Trademark Office ("PTO"). U.S. Patent 9,512,418 B2 (the "'418 Patent") claims a method for production of botulinum toxin. The problem for Daewoong is that the core inventions claimed in the '418 Patent were conceived and developed by Medytox researchers and belong to Medytox.

4. The fact that Daewoong misappropriated Medytox's manufacturing process trade secrets and used them to develop the manufacturing process that it claims as its own has already been determined by the U.S. International Trade Commission ("ITC"). The ITC conducted a thorough investigation into the events concerning Daewoong's misappropriation, and determined that Medytox's proprietary manufacturing process trade secrets were misappropriated and used by Daewoong, and its partner in the U.S., Evolus, Inc. ("Evolus"). *See In re Certain Botulinum Toxin Products, Processes for Manufacturing or Relating to Same and Certain Products Containing Same*, U.S. ITC Inv. 337-TA-1145 (the "ITC Investigation").

5. The ITC found that Daewoong and Evolus violated section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) through the misappropriation of Medytox's manufacturing process trade secrets in the development of Daewoong's BTX product.[1] This finding is made in the ITC Final Determination (the "Comm'n Op.") and Final Initial Determination (the "FID"). A copy of the public ITC Commission Opinion is attached as Exhibit A, and the public Final Initial Determination by the ITC Administrative Law Judge ("ALJ") is attached as Exhibit B.

6. In addition to stealing Medytox's trade secret inventions, Daewoong had the audacity to claim them as its own. [redacted]

[1] On February 18, 2021, Allergan and Medytox reached a settlement with Evolus that grants Evolus a license to import and sell the products at issue in the ITC Investigation. This settlement resulted in the rescission of the ITC's remedial orders banning Jeuveau from importation and sale for 21 months. Daewoong is not a party to that settlement and thus is not a "party to the mutual releases of liability, covenants not to sue, or licenses granted to Evolus." *Certain Botulinum Toxin Prods., Processes for Mfg. or Relating to Same and Certain Prods. Containing Same*, Inv. No. 337-TA-1145, USITC Pub. 735885, Joint Pet. of Complainants Medytox and Allergan and Resp't Evolus to Rescind the Limited Exclusion Order and the Cease and Desist Order, Exhibit B at ¶ ¶ 8.1, 11.1 (Mar. 3, 2021) ("Settlement Agreement"). To the contrary, the Settlement Agreement expressly provides that "[n]othing in this Agreement creates any right enforceable by Daewoong." *Id.* at 11.1.

[redacted]

7. Medytox brings this lawsuit to correct the errors in inventorship in the '418 Patent by including Dr. Jung and Mr. Kim as inventors. Medytox also seeks the equitable assignment of Daewoong's ownership rights in the '418 Patent to Medytox based on the fact that Daewoong obtained the '418 Patent by wrongfully taking Medytox's manufacturing process inventions and claiming them as its own.

8. The factual and legal predicate of the claims asserted here – Daewoong's misappropriation of the Medytox trade secrets and use of them to develop the manufacturing process that it claims as its own – has been fully litigated and adjudicated on the merits in the ITC, and that determination is entitled to issue preclusive effect in this lawsuit.[2]

[2] Medytox brought a suit in 2017 in a California state court to address Daewoong's misappropriation of the Medytox trade secrets and its partnership with Evolus to exploit those trade secrets. The state court granted a *forum non conveniens* motion by the defendants, based principally on the premise that the relevant documents and witnesses were located in Korea and so it would be burdensome to address the claims in a U.S. lawsuit. The state court ultimately dismissed the claims against Daewoong and stayed the claims against Evolus and the other non-Korean defendants.

When Evolus subsequently obtained FDA approval to introduce Daewoong's aesthetic BTX products in the U.S., it became appropriate for Medytox (together with its co-complainant, Allergan) to bring an ITC case against Daewoong and Evolus to address the harm that their unfair acts would cause to the legitimate BTX industry in this country. In the ITC case, the parties took discovery of the relevant documents and witnesses and developed a complete evidentiary record and, based on that evidentiary record, the fact that Daewoong misappropriated Medytox's manufacturing process trade secrets and used them to develop its manufacturing process has been adjudicated. This determination is entitled to issue preclusive effect here.

II. PARTIES

A. Medytox

9. Plaintiff Medytox is a limited liability corporation incorporated under the laws of the Republic of Korea ("Korea"). Its principal place of business is located at 626 Tehran Road, Gangnam, Seoul, Korea. A subsidiary of Medytox maintains offices in the United States at Olympic Plaza, 11500 W. Olympic Blvd., Suite 400, Los Angeles, California 90064. Medytox shares trade on the KOSDAQ under the code "086900."

10. Medytox was founded in 2000 for the purpose of researching, developing, and manufacturing BTX products. The Chief Executive Officer ("CEO") of Medytox, Dr. Hyun Ho Jung, obtained rights in 1999 to a unique variant of the Hall A-hyper strain, the *C. botulinum* strain that Medytox uses to produce its BTX products. As the ITC has found to have been established by the evidentiary record, Medytox spent years conducting research and development on both its strain and on proprietary manufacturing processes to create a commercial BTX product using that strain. Ex. B (FID at 117). These efforts led to the development of not only Meditoxin, the first domestically-developed BTX product in Korea, but several other BTX products that have received regulatory approval in various jurisdictions around the world. Medytox is a biopharmaceutical company that pioneered the development of botulinum toxin type A drugs in Korea. Medytox owns the bacterial strain, trade secrets, and confidential information relating to its R&D efforts, which were stolen by Daewoong.

11. Medytox is the assignee of the rights and interests of its employees sought to be added as inventors of the inventions claimed in the '418 Patent.

B. Daewoong

12. Defendant Daewoong Co., Ltd. is a limited liability corporation organized under the laws of the Republic of Korea. Defendant Daewoong Pharmaceutical Co., Ltd. is a limited liability corporation organized under the laws of the Republic of Korea having its principal place of business at Bongeunsaro 114-gil 12, Gangnam, Seoul, Korea. Medytox is informed and believes that Daewoong Co., Ltd. holds a controlling interest in Defendant Daewoong Pharmaceutical Co., Ltd. Daewoong Pharmaceutical Co., Ltd. manufactures BTX products known as DWP-450 (marketed as Jeuveau in the United States and Nabota in Korea) and ABP-450 (currently pending approval for sale in the United States).

13. Daewoong Co., Ltd. is the assignee of the '418 Patent by virtue of assignment from the named inventors on the '418 Patent. *See* '418 Patent at 1, item [73].

III. OTHER RELEVANT PERSONS

14. Dr. Hyun Ho Jung is an individual residing in Korea. Dr. Jung is the CEO of Medytox. Dr. Jung is a former university professor who has dedicated his career to the study of the C. botulinum bacteria, and founded Medytox in 2000 to continue his research and development efforts related to toxins derived from C. botulinum. Dr. Jung provided the original sample of the bacterial strain that underlies all of Medytox's BTX products and research. Dr. Jung graduated from Seoul National University in 1986, received a master's degree from the Korean Advanced Institute of Science and Technology ("KAIST") in 1988, and received a Ph.D. in toxinology from KAIST in 1992 and later worked as a professor at Sun Moon University. At all times since the formation of Medytox, Dr. Jung has overseen and participated in Medytox's development of its manufacturing processes.

15. Hack Woo Kim is an individual residing in Korea. Mr. Kim is a director at Medytox. Mr. Kim began work at Medytox in March 2001, and was the company's fourth employee. His work primarily focused on developing the process to extract and purify the botulinum toxin protein complex from the *C. botulinum* strain as part of Medytox's research and development of its Meditoxin product, as well as others. Mr. Kim holds a bachelor's degree in Food Science and Biotechnology from Kyonggi University, and a master's degree in biotechnology from Yonsei University. Since he began at Medytox, Mr. Kim has at all times participated in Medytox's development of its manufacturing processes.

16. Dr. Hyun Ho Jung and Mr. Hack Woo Kim, collectively referred to as the "Medytox Inventors," have both assigned to Medytox any and all rights to the technologies, inventions, know-how, works, or patents that are the subject of this litigation.

17. On information and belief, Chung Sei Kim is an individual residing in Korea. Chung Sei Kim is a listed inventor of the '418 Patent.

18. On information and belief, Young Song is an individual residing in Korea. Young Song is a listed inventor of the '418 Patent.

19. On information and belief, Kyoung Min Min is an individual residing in Korea. Kyoung Min Min is a listed inventor of the '418 Patent.

20. On information and belief, Young Duk An is an individual residing in Korea. Young Duk An is a listed inventor of the '418 Patent.

21. Chung Sei Kim, Young Song, Kyoung Min Min, and Young Duk An will be collectively referred to as the "Daewoong Inventors."

IV. JURISDICTION AND VENUE

22. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

23. This action arises under the laws of the United States of America, including by raising a substantial question of federal law with respect to the requested correction of the named inventors of a U.S. patent and the equitable assignment of ownership of the patent. *See* 28 U.S.C. §§ 1331, 1338(a); *see also* 35 U.S.C. §§ l00(a), 116, 152 & 261.

24. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b) and (d).

25. This Court has personal jurisdiction over Daewoong to adjudicate this action, which arises out of activities that Daewoong purposefully directed at and participated in in the Eastern District of Virginia, including Daewoong's filing and prosecution of the patent application that resulted in the '418 Patent at the U.S. Patent and Trademark Office, headquartered in Alexandria, Virginia.

V. FACTUAL ALLEGATIONS

26. The facts establishing Medytox's claims are set forth in greater detail below. As reflected in the citations to the Commission Opinion and the ALJ's FID, which the Commission Opinion affirmed in relevant part, the allegations set forth below have been adjudicated by the ITC and therefore are established for purposes of this suit as a matter of issue preclusion. Further, even if the ITC's findings were not entitled to preclusive effect, the evidence that led to the ITC's findings would lead to the same findings here. References to the Final Initial Determination and Commission Opinion are alleged both as factual allegations in this lawsuit as well as to demonstrate that the ITC's rulings have adjudicated these facts as established and therefore they are entitled to issue preclusive effect.

A. Background on the Technology

27. BTX products are made from *C. botulinum*, which produces a highly potent neurotoxin that can cause muscle paralysis and death and must be carefully handled. *C. botulinum* is the bacteria that causes botulism. Ex. A (Comm'n Op.) at 5–6. BTX products have both therapeutic applications, including the treatment of chronic migraine headaches, cervical dystonia, hyperhidrosis, spasticity, and urinary incontinence, and aesthetic applications, including the temporary improvement to the appearance of glabellar lines (sometimes called frown lines), lateral canthal lines (sometimes called crow's feet), and forehead lines. *Id.* at 5. In a typical cosmetic procedure, a 50-unit or 100-unit vial of a BTX product is injected via syringe into the muscle of the target area. The BTX product operates as a neuromuscular blocking agent, which functions by temporarily interfering with nerve signals and temporarily relaxing targeted muscles through localized injections. *Id.* at 5.

28. All BTX products require use of a commercially viable *C. botulinum* strain. *Id.* at 6. Different strains of *C. botulinum* produce different serotypes of neurotoxin. *Id.* The serotypes have been labeled alphabetically from serotype A to serotype G, and there are subtypes within each serotype (e.g., A1, A2, etc.). *Id.* Type A1 BTX products are the most commercially viable. *Id.* at 25. However, not every Type A1-producing strain can be used to make a commercial product; the properties of the strain are exceptionally important when considering whether it can be used for a commercial product. *Id.*

29. In addition to requiring a strain, producing a BTX product requires a carefully calibrated manufacturing process. Ex. A (Comm'n Op. at 6). The manufacturing process for BTX products includes the manufacturing of the drug substance (also called the API or the "bulk") and the drug product (the finished dosage form sold to consumers). Manufacture of the

BTX drug substance involves culturing the *C. botulinum* bacteria, and then separating, isolating, and purifying the neurotoxin complex. *Id*. When cultured (i.e., grown), the *C. botulinum* bacteria secrete the neurotoxin protein molecule along with several other neurotoxin associated proteins. *Id.* These collectively, together with the neurotoxin protein molecule, form the whole protein complex, which is called the neurotoxin complex. *Id.* The molecular weight of this whole neurotoxin complex can vary, but the largest size is 900 kDa. *Id.* The whole neurotoxin complex can be used for a BTX product. The neurotoxin complex can also be further purified, if desired, to varying degrees until all the proteins, with the exception of the neurotoxin protein molecule, are removed.

30. The BTX products of Medytox, Daewoong, and Evolus all use the neurotoxin complex with a molecular weight of 900 kDa. *Id.*

31. After the drug substance is obtained, it must be formulated and packaged into the final drug product (i.e., a form that can be used by and sold to clinicians). Production of the drug product involves combining the drug substance with additional ingredients known as excipients, which are used to stabilize the neurotoxin molecules and provide a sterile preparation of the product for injection. Ex. B (FID at 10).

32. BTX products can be sold in either a solid or liquid form using a variety of excipients. The solid forms can be a powder that is either freeze-dried (or "lyophilized") or vacuum-dried, which must be diluted with a suitable liquid prior to injection. The liquid forms do not require this step and can be injected directly. Ex. B (FID at 11).

B. The ITC Investigation

33. Medytox has proven the misappropriation of its trade secrets in litigation before the ITC pursuant to section 337 of the Tariff Act of 1930.

34. On January 30, 2019, Medytox, and its U.S. partner, Allergan plc and Allergan Inc. (together "Allergan"), commenced an action in the ITC after uncovering evidence that Daewoong had misappropriated Medytox's bacterial strain and processes for manufacturing BTX products, and used Medytox's trade secrets to manufacture, import and sell DWP-450 in the United States.

35. After nearly a year of discovery, an evidentiary hearing was conducted from February 4-7, 2020, after which the parties (including the Office of Unfair Import Investigations) submitted over a thousand pages of post-hearing briefing.

36. On this record, July 6, 2020, the Administrative Law Judge ("ALJ") issued a 274-page Final Initial Determination finding, among other things, that Daewoong misappropriated Medytox's manufacturing process trade secrets and used them to develop the BTX manufacturing product that it claims as its own and used to make its BTX products, in violation of section 337 of the Tariff Act of 1930 (19 U.S.C. § 337).

37. On December 16, 2020, the full Commission issued a Final Determination that "affirm[ed] the FID's findings regarding the existence and misappropriation of Medytox's trade secrets relating to its manufacturing process." Ex. A (Comm'n Op. at 44). The ITC found that Daewoong misappropriated Medytox's manufacturing process trade secrets in the development of its BTX product, DWP-450, in violation of section 337 of the Tariff Act of 1930 (19 U.S.C. § 337). The ITC also found that Daewoong had improperly obtained Medytox's *C. botulinum* strain and used it to make DWP-450, but declined to find a violation of Section 337 as to the Medytox strain based on its view that prior transfers of the strain rendered it ineligible for trade secret protection.[3]

[3] Medytox and Daewoong have both appealed certain aspects of the ITC's determination to the United States Court of Appeals for the Federal Circuit.

C. Medytox's Manufacturing Processes Constitute Protectable Trade Secrets

38. Daewoong misappropriated certain of Medytox's manufacturing process trade secrets for BTX products, including Meditoxin, Innotox, and MT10109L.

39. Meditoxin is a 900 kDa BTX product that has been licensed worldwide for both cosmetic and therapeutic indications and has received approvals in more than 30 countries. Also at issue is Medytox's further R&D that has been incorporated into the development of new products, including Innotox and MT10109L. Innotox and MT10109L are also 900 kDa BTX products, but unlike others they are manufactured without the use of animal-derived components. Medytox has a licensing agreement with Allergan to jointly develop, commercialize, and sell the MT10109L product in the United States.

40. "Medytox's manufacturing process information reflects Medytox's R&D and its decisions, following years of extensive experimentation on the optimal method for manufacturing a commercial BTX product, about what to include in a proprietary, commercially viable manufacturing process." Ex. B (FID at 121-22). As a result, "Medytox's manufacturing process for producing toxin from its Hall A-hyper strain and purifying it into a drug substance is valuable to Medytox, and would be valuable to its competitors." *Id.* at 122.

41. It took more than four years and millions of dollars for Medytox to conduct the R&D necessary to "optimize a manufacturing process for the final purified toxin that is packaged into the final botulinum product of Meditoxin." *Id.* at 123.

42. Medytox's "development process began with an extensive and documented review of available academic literature regarding isolation and purification of BTX." *Id.* at 127-28. Medytox took what was available from the academic literature and began its own R&D program to develop a commercial BTX product. Medytox recorded the various versions of its

processes in batch records, which reflect "not only information concerning each individual step in the manufacturing process but also how those steps fit together." *Id.* at 128. These "batch records contain several elements that Medytox claims as trade secrets" including the trade secrets that Daewoong misappropriated. Ex. B (FID at 129, 132-147).

43. Medytox used the Meditoxin manufacturing process as the starting point for extensive experimentation to further improve its manufacturing process, which resulted in several innovations. For example, "Medytox experimented with simplifying the purification process … [and optimizing] the potency of the neurotoxin." Ex. B (FID at 129).

44. As a result of these significant efforts, "Medytox owns its method for producing neurotoxin complex from its Hall A-hyper strain and purifying it into a commercially viable drug substance." Ex. B (FID at 127).

45. And Medytox also protected these trade secrets. "Medytox has always closely guarded its proprietary, confidential manufacturing process information" through physical security measures, confidentiality agreements and IT security systems. Ex. B (FID at 120-121).

46. Medytox's manufacturing processes are entitled to trade secret protection because they are not known in the industry, and could not easily be acquired or duplicated. Ex. B (FID at 117, 127-29). Rather, Medytox's manufacturing "information and processes that have significant commercial value, reflecting years of Medytox R&D that are not publicly available and have never been publicly disclosed. That companies jealously guard and protect information relating to their manufacturing process as a valuable asset is well-accepted." Ex. B (FID at 117) (citations omitted).

47. Similarly, Daewoong "did not [and cannot] offer any admissible evidence … of a publication or other disclosure in the public domain that combines each of the constituent

elements of the Medytox manufacturing processes in the specific combination as utilized and asserted by Medytox." Ex. B (FID at 118). Rather, "no single reference [in the literature] discloses each of the specific elements of the Medytox manufacturing processes, or the specific elements in the specific stages of Medytox's manufacturing process." *Id.* at 119.

D. Daewoong's Misappropriation Of Medytox's Manufacturing Processes

48. "Daewoong misappropriated Medytox's trade secrets in its manufacturing processes" for its BTX products. Ex. A (Comm'n Op. at 41).

49. The "evidence establishes that [a former Medytox employee] had access to, and knowledge of, numerous details of Medytox's manufacturing process, and also worked with Daewoong when it was trying to develop its own process." *Id.*

50. At the outset of its project to develop a BTX product, Daewoong engaged as a consultant this former employee of Medytox, who had a thorough knowledge of the Medytox manufacturing process trade secrets, as well as access to and possession of materials containing Medytox trade secrets. That former employee owed a duty to Medytox to keep these trade secrets confidential and to assign to it the fruits of any research and development and inventive contributions relating to his work for Medytox. *See id.*, Ex. B (FID at 121, 132).

51. At least three factors demonstrate that the Daewoong manufacturing process is derived from, and in many ways identical to, Medytox's trade secret process: "(1) the similarity of Daewoong's process to Medytox's; (2) the lack of evidence of Daewoong's independent development; and (3) the implausibly fast timeline by which Daewoong achieved BTX production at commercial scale." Ex. A (Comm'n Op. at 41), Ex. B (FID at 132).

52. First, "Daewoong's manufacturing process substantially overlaps with Medytox's manufacturing process." Ex. A (Comm'n Op. at 41). "The similarities between the Daewoong

and Medytox processes cannot be coincidence." Ex. B (FID at 136). In particular, there are "three key similarities" between the Daewoong and Medytox processes. *Id.*

53. Second, "Daewoong has not provide[d] sufficient evidence demonstrating its own independent development of its manufacturing process." Ex. A (Comm'n Op. at 43); Ex. B (FID at 148). Instead of the extensive R&D one would expect from a large pharmaceutical company, Daewoong "lack[s] any contemporaneous documentation of citations to the disparate published scientific literature dating back to as early as the 1940s on which Daewoong purportedly relied to piece together the steps of the manufacturing process for the DWP-450 drug substance." Ex. A (Comm'n Op. at 43). Most notably, "[o]nly a handful of lab notebooks … pertain to the development work for DWP-450," and this "lack of contemporaneous research and development records" is "highly unusual for a pharmaceutical company, especially when the drug is successfully brought to market." Ex. B (FID at 141). Similarly, the contents of the notebooks "do not demonstrate independent development of the drug substance [and] Daewoong cannot argue the deficiency in its records should be attributed to the passage of time." *Id.* at 143.

54. When contrasted against the "voluminous documents [produced by Medytox] demonstrating its R&D, [which] … clearly support Medytox's use of academic literature to develop its manufacturing processes," there can be no doubt that Daewoong did not develop its own process. Ex. B (FID at 147).

55. Finally, Daewoong's development of its process was far too short to support independent development, especially given the lack of BTX experience by Daewoong's research and development team. Ex. B (FID at 148); *see also id.* at 151-52 ("From a practical standpoint, such a schedule could not be achieved through independent development from scratch. This is particularly the case in view of team's lack of BTX experience, the purported development work

was done by an intern, and the minimal amount of actual development activity recorded in that time span."). As a result, "it is not credible to reach the milestone of a commercial scale batch in such a short period of time." *See id*. at 148.

E. Daewoong Used Medytox's Trade Secrets to Apply For and Obtain the '418 Patent

56. After having stolen Medytox's innovative manufacturing process trade secrets, [redacted]

57. Daewoong's application for a U.S. patent on a method of producing botulinum toxin culminated in the issuance of the '418 Patent on December 6, 2016.

58. [redacted]

59. Claim 1 of the '418 Patent, which is the only independent claim, claims "[a] method for production of botulinum toxin … the method comprising the steps of:

a) treating a culture of a botulinum toxin-producing strain with acid to precipitate a botulinum toxin;

b) adding buffer to the precipitated botulinum toxin, followed by treatment with a protease inhibitor and nuclease, thereby extracting the botulinum toxin;

c) treating the extracted botulinum toxin with acid to precipitate the botulinum toxin and dissolving the precipitate in buffer; and

d) purifying the botulinum toxin by anion exchange chromatography, wherein the acid precipitation of step (c) is performed by adding sulfuric acid or hydrochloric acid to the extracted botulinum toxin, so that the extracted botulinum toxin reaches a pH of 2.5 -4.5."

60. A true and accurate copy of the '418 Patent is attached as Exhibit C.

61. In its application for the '418 Patent, Daewoong listed only the Daewoong Inventors (Chung Sei Kim, Young Song, Kyoung Min Min, and Yeong Duk An), and failed to identify the Medytox Inventors (Dr. Hyun Ho Jung and Mr. Hack Woo Kim) whose inventive contributions were misappropriated by Daewoong.

62. The Medytox Inventors did more than merely provide well-known principles or explain the state of the art. Through their efforts in conceiving and developing the Medytox manufacturing processes, the Medytox Inventors contributed their ideas to the total inventive concept that is claimed in the '418 Patent, as well key inventive elements of each claim.

63. At the outset of its project to obtain a BTX manufacturing process, Daewoong misappropriated and used Medytox's trade secret process for producing Meditoxin. Critically, as the ITC found, "Daewoong's first run of a manufacturing process in August 2010 copies the Meditoxin process." Ex. B (FID at 134). Thus, at the very root and beginning of Daewoong's purported development process, it copied and used the Medytox manufacturing process trade secrets used to make its Meditoxin product.

64. Daewoong misappropriated and used core elements of the manufacturing process for Meditoxin, as well as further innovations that Medytox developed through its further research and development efforts in connection with the development of Innotox and MT10109L. Further, a side-by-side comparison reveals that "Daewoong's [final] manufacturing process [] substantially overlaps with Medytox's." *Id.* [redacted]

[redacted]

65. Still further, in the prosecution of the '418 Patent, [redacted]

F. Medytox's Voluminous Records Corroborate The Contributions Of The Medytox Inventors To The Claims In The '418 Patent

66. In addition to the findings of the ITC, Medytox's voluminous records corroborate the significant contributions of the Medytox Inventors to the conception, and reduction to practice, of the claims in the '418 Patent. Ex. B (FID at 147).

67. These records show that Dr. Hyun Ho Jung spent years conducting extensive research and development of a manufacturing process that would transform the deadly toxin produced by its *C. botulinum* strain into a commercial product safe for human use. *Id.* at 123-26. These efforts resulted in an optimized manufacturing process for producing the drug substance used in Medytox's first commercial BTX product, Meditoxin. *Id.* The development of this manufacturing process took more than four years of Dr. Jung's experimentation and that of Medytox's R&D team over which Dr. Jung had oversight, from the initial research and development phase to the grant of regulatory approval of Meditoxin. *Id.* From there, Dr. Jung and his research team, including Mr. Kim, created new innovations through their research to develop the manufacturing processes for Medytox's Innotox and MT10109L products.

68. At a high-level, the drug substance manufacturing process for a BTX product can be divided into three phases: (1) culturing the strain, which involves creating a "medium"

containing essential nutrients that allows the C. botulinum strain to replicate so that there is enough of it for use in research and/or commercial production; (2) separating the neurotoxin released into the culturing medium from the undesirable substances involved in this process, including other proteins and any remaining bacteria; and (3) purifying the neurotoxin, which involves multiple additional processes to remove finer pollutants from the drug substance so that what is left is a pure drug substance. *Id.* at 10-11. Once the drug substance is created, a separate manufacturing process is used to incorporate this drug substance into a final drug product that can be administered for aesthetic or therapeutic purposes. *Id.* at 11.

69. When Dr. Jung and Medytox first began their research and development efforts for Medytox's drug substance manufacturing process, existing academic literature described only how type A botulinum toxin drug substance could be produced for research purposes, and even then only in general terms – no process described in literature was independently sufficient to produce a commercially viable BTX product capable of obtaining regulatory approval. *Id.* at 127 ("[N]o single reference cited by [Daewoong] discloses each of the specific elements of the Medytox manufacturing processes, or the specific elements in the specific stages of Medytox's manufacturing process.").

70. When Medytox was founded, Allergan and Ipsen were the only two companies in the world to have successfully manufactured a BTX product from a BTX Strain and their manufacturing processes were not publicly known. Even now, companies zealously guard the secrecy of their BTX product manufacturing processes, and no publicly available literature provides the technical know-how and processes required to commercialize a BTX product. *Id.* at 117-118.

71. Developing the manufacturing process for the Meditoxin drug substance therefore required meticulous, time-consuming, and expensive research and development efforts. In particular, "the separation and purification process, which involves separating the cultured neurotoxin complex from the undesirable substances contained in the culture medium and using a variety of chemical compounds and techniques to remove finer pollutants from the drug substance, is the most difficult portion of the drug substance manufacturing process to develop." Ex. B (FID at 123). The precise steps in the separation and purification processes had to be designed by highly skilled researchers like Dr. Jung and Mr. Kim who were familiar with the various fermentation, precipitation, and filtration techniques that could be used to accomplish separation and purification. Those precise steps had to then be run over and over again to generate test results and ascertain whether the steps must be altered or rearranged. And every time a step was altered or rearranged, the entire process had to be run again numerous times to verify that the resultant product was improved by the change.

72. Not only did the correct steps and correct order of steps have to be determined, the Medytox researchers "conducted focused experiments to optimize the process and parameters at each point in the manufacturing process, which consisted of altering the process parameters … of various steps in the process to determine whether the change had a positive or negative effect on the quality of the drug substance produced." Ex. B (FID at 124). And again, for each change made to a process parameter, the entire process had to be run numerous times to verify that a change in a parameter in one step did not produce unintended negative consequences in later steps.

73. "This iterative process was extremely complicated for many reasons, including the fact that a change in any step of the manufacturing process could have unexpected

interactions with other steps in the process." Ex. B (FID at 125). "Several rounds of testing of the entire process were therefore required whenever any part of any individual step was changed. The resultant drug substance also had to be tested at various points in the process after every change to ensure that that change improved the overall quality of the drug substance." *Id.* (citations omitted). This quality testing added another layer of difficulty into the research and development process.

74. Dr. Jung, and the R&D team he directly supervised, including Mr. Kim, conducted extensive research and development [redacted] As a result, Medytox was only able to develop and obtain regulatory approval for Meditoxin in Korea in March 2006. [redacted] "Medytox used the Meditoxin manufacturing process as the starting point for extensive experimentation to improve its manufacturing process, which resulted in several innovations." Ex. B (FID at 126). [redacted]

75. The contributions of Dr. Jung and Mr. Kim are captured in Medytox's records, and reflect their oversight and contributions to all of Medytox's innovations.

76. The Medytox Inventors made these significant inventive contributions based on years of careful experimentation and research. Dr. Jung, as founder and CEO of Medytox and a pioneering researcher into *C. botulinum*, conducted experiments that laid the foundation for all of Medytox's industrial-scale production of BTX. Under Dr. Jung's leadership, Medytox's R&D team, including Mr. Kim, continued his work to develop the Meditoxin drug substance

manufacturing process and the subsequent, additional innovations to that process. Dr. Jung directly and substantively supervised each developmental stage of Medytox's R&D program. Under Dr. Jung's leadership and as a key member of Medytox's R&D team from the early days of its R&D program, Hack Woo Kim also contributed to each development of Medytox's innovative processes. The portions of the process claimed in the '418 Patent that were taken from Medytox (which will be disclosed under the protection of a confidentiality order) constitute the inventive contribution of Dr. Jung and Mr. Kim. Accordingly, Dr. Jung and Mr. Kim should be included as named inventors.

COUNT I

(Correction of Inventorship of U.S. Patent No. 9,512,418 B2 Pursuant to 35 U.S.C. 256)

77. Medytox hereby re-alleges and incorporates by reference the foregoing paragraphs of the Complaint as if fully set forth herein.

78. Dr. Hyun Ho Jung and Mr. Hack Woo Kim each made significant inventive contributions to the conception of the subject matter claimed in the '418 Patent.

79. Dr. Hyun Ho Jung and Mr. Hack Woo Kim are joint inventors of the '418 Patent and accordingly should be named as inventors of the patent.

COUNT II

(Equitable Assignment of '418 Patent)

80. Medytox hereby re-alleges and incorporates by reference the foregoing paragraphs of the Complaint as if fully set forth herein.

81. Medytox is the owner of the BTX manufacturing process trade secrets that Daewoong misappropriated and used to obtain the '418 Patent. The existence of Medytox's

trade secrets and Daewoong's misappropriation has already been fully litigated and adjudicated on the merits, and that determination is entitled to preclusive effect in this lawsuit.

82. Medytox developed its manufacturing process trade secrets through years of research and development. These trade secrets derive independent economic value from being kept a secret, and not being readily ascertainable through proper means.

83. At all relevant times, Medytox has taken reasonable measures to keep the information secret.

84. As a result of the conduct and events described in detail above, including Daewoong's misappropriation of Medytox's manufacturing process trade secrets and use of them to obtain the '418 Patent, Medytox is entitled to equitable assignment of the ownership of the '418 Patent to it.

COUNT III

(Declaratory Judgment Pursuant to 28 U.S.C. §§ 2201 and 2202)

85. Medytox hereby re-alleges and incorporates by reference the foregoing paragraphs of the Complaint as if fully set forth herein.

86. There exists an actual, ripe, and justiciable controversy between Medytox and Daewoong concerning the inventorship of '418 Patent, and each party's rights, as well as the interests and ownership rights of the '418 Patent.

87. As a result of the conduct and events described in detail above, Medytox seeks a declaratory judgment from this court that Dr. Jung and Mr. Kim should be included as inventors on the '418 Patent.

88. Medytox also seeks a declaratory judgment that Medytox is entitled to equitable assignment of the ownership and/or other interests in the '418 Patent, as well as any relief necessary to inforce Medytox's rights under that declaratory judgment.

89. Resolution of this Count necessarily depends on the resolution of a substantial question of federal law, including patent law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Medytox requests that the Court grant the following relief:

1. Determine and declare that Dr. Hyun Ho Jung and Mr. Hack Woo Kim are joint inventors of the '418 Patent;
2. Order the United States Patent and Trademark Office to correct the inventorship of the '418 Patent by adding Dr. Hyun Ho Jung and Mr. Hack Woo Kim as joint inventors;
3. Order Daewoong to assign all ownership rights to '418 Patent to Medytox; and
4. Grant Medytox such other and further relief that this Court deems is just and proper.

Dated: May 14, 2021

Respectfully submitted,

By: /s/ *Chad E. Kurtz*

Thomas J. Fisher (VSB No. 44062)
Chad E. Kurtz (VSB No. 88863)
Cozen O'Connor
1200 19th Street, NW
Washington D.C. 20036
Telephone: (202) 912-4800

David H. Herrington (*pro hac vice to be filed*)
Arminda B. Bepko (*pro hac vice to be filed*)
Cleary Gottlieb Steen & Hamilton LLP
One Liberty Plaza
New York, NY 10006
Telephone: (212) 225-2000

Nowell D. Bamberger (*pro hac vice to be filed*)
Cleary Gottlieb Steen & Hamilton LLP
2112 Pennsylvania Avenue, N.W.
Washington, D.C. 20037
Telephone: (202) 974-1500

Attorneys for Plaintiff Medytox Inc.